Title: HYDROTHERAPY COMPARED WITH PEG-ES LAVAGE AND AQUEOUS SODIUM PHOSPHATE AS BOWEL PREPARATION FOR ELECTIVE COLONOSCOPY: A PROSPECTIVE, RANDOMIZED, SINGLE BLINDED TRAIL.

Purpose: Hydrotherapy is a method of colon cleansing using constant warm water lavage using a contained temperature and pressure controlled device administered by a trained technician. The aim of this study was to compare the efficacy and patient acceptance of same-day hydrotherapy (HYDRO) with polyethylene glycol-electrolyte lavage (PEG-ES) and aqueous sodium phosphate (ASP) in patients undergoing elective colonoscopy.

Methods: Consecutive outpatients referred for elective colonoscopy were randomly assigned to receive 4 L PEG-ES (n=55) two doses of aqueous sodium phosphate (n=52) or same day hydrotherapy (n=53), as bowel preparation. The endoscopists were blinded to the method of preparation. The overall quality of the colon cleansing was evaluated with respect to the adequacy of visualization of the right, transverse and left colon. Patients were asked to rate the preparation with respect to ease, convenience, and comfort using structered, validated questionnaire. Results were analyzed using the chi square test.

Results: Endoscopists rated the quality of colon cleansing as good for the right: 62% ASP, 49% PEG-ES, and 92% HYDRO (p<0.001). For the transverse colon: 80% Asp, 63% PEG-ES and 100% HYDRO (p<0.001). For the left colon: 84% ASP, 67% PEG-ES and 98% HYDRO (p<0.001). Patients rated the preparations as easy: 87% ASP, 56% PEG-ES, and 96% HYDRO (p<0.001). Patients rated convenience: 61% ASP, 79% PEG-ES, and 98% HYDRO (p<0.001). Patients rated for comfort: 71% ASP, 36% PEG-ES, and 94% HYDRO (p<0.001). Patients were asked if they wanted a different preparation for the next colonoscopy: 48% ASP, 60% PEG-ES, and 4% HYDRO (p<0.001).

Conclusion: The quality of colon cleansing, overall tolerance, comfort and convenience were significantly better for HYDRO. In this study ASP was better than PEG-ES for the same parameters. Hydrotherapy should be further investigated as a viable alternative to PEG-ES and ASP for bowel preparation prior to colonoscopy.

*Manufacturer’s note: The equipment used in this study was the Toxygen Model BSC-UV, a “closed system” manufactured by Dotolo Research Corp. The Dotolo Colon Irrigation system has been cleared by the FDA for the intended use as described in this study.
Effects of Colon Hydrotherapy on Serum Electrolytes
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Introduction
Colon hydrotherapy is a traditional naturopathic technique frequently used in the preparation for colorectal endoscopy, radiology, and surgery, and for the treatment of constipation and various disorders associated with chronic endotoxemia of fecal origin. Several published reports have described significant, sometimes fatal water and electrolyte imbalances following enemas or colonic irrigation. In most of these, the complications had occurred in patients with either neurogenic constipation such as cord lesion or congenital megacolon, or advanced disseminated malignancy. We evaluated the effect of a traditional colonic irrigation technique on ambulatory patients who were free of serious pathology, comparing weight, serum electrolyte concentrations before and after a series of three colonic treatments given in a one week period.

Methods
Seventeen volunteers (11 females, 6 males) ages ranging from 22-54 were recruited by advertisement from the student externs and patient population at the Portland Naturopathic Clinic. Pre-experiment history and physical examination were performed to exclude any person with cardiovascular including hypertension, congestive heart failure and angina, renal, or metabolic disease, bowel obstruction or inflammatory bowel disease. Serum electrolytes were measured by a single reference laboratory, using an automated multichannel instrument, prior to the first treatment and immediately before and after the third treatment.

Treatments were all administered by trained personnel using the Dotolo Model 1085-SV Colon Hydrotherapy Instrument. Infusion pressure was limited to less than 1.25 pounds per square inch, and the number of fill-empty cycles was recorded for each treatment. The water was retained and released under operator control according to patient comfort. Each treatment consisted of repeated fill-empty cycles for approximately 45 to 60 minutes. Abdominal massage was applied during the evacuation phase of each cycle according to patient comfort. Patients were placed in the supine or left lateral decubitus position throughout the treatment. After treatment, the patient was instructed to evacuate remaining stool and water in a sitting position prior to post-treatment measurement. Serum electrolyte values were evaluated by a one-way analysis of variance for comparisons between the three groups.
Results
No patients experienced any clinically significant complications or complaints during or after the course of treatment. The laboratory results for the three sets of tests (baseline, immediately prior to 3rd treatment, and immediately following the 3rd treatment) are presented in Figures 1-5, and summarized in Table 1.

The abnormalities found in this data are the following: a slightly elevated serum potassium in one patient recorded after the third treatment, and low serum sodium in a second individual (this was noted in both the second and third serum samples. Three individuals had slightly elevated serum phosphorus levels (two on one occasion, the other twice). Four individuals had slightly elevated chloride levels (one sample each). None of these patients experienced signs or symptoms of water or electrolyte imbalance.

There was no statistical significance in the between treatment values for serum Calcium, Potassium, or Phosphorus. However, variance in both serum Sodium and Chloride levels were significant; Chloride at the .05 level, and Sodium at the .01 level. While statistically significant neither the means nor the individual serum levels dropped to values which would be considered clinically significant.

Discussion
In the present study, 17 volunteers with no history of serious disease or bowel pathology were subjected to moderately vigorous colonic irrigation without causing significant symptoms or disturbances in serum electrolytes. The frequency and technique of treatments was chosen to represent practice among naturopathic physicians and colon hydrotherapists.

While this study provides grounds for safe use of colon hydrotherapy with certain patients, it does not address those situations in which a risk of water intoxication is high. Ziskind and Gellis in 1959 provided the first criteria for assessing risk of water intoxication via enema. They were unable to demonstrate electrolyte or clinical complications following water enemas of a volume equivalent to 3.5% of body weight in 11 children with "normal" colon function. On the contrary, they reported five cases of electrolyte imbalance following rectal infusion of water equivalent to 2.5% to 3.5% body weight in children with congenital megacolon or chronic atonic constipation. They also reported one case of severe electrolyte imbalance in a febrile child given seven enemas in four hours totaling over 60% of body weight. This child had no history of bowel disorders, but was having febrile seizures before and during the series of enemas. In 1976, Jacob et al. described death due to hyponatremia and bowel perforation in a 14 month-old girl without prior bowel abnormality following enemas of 9% of body weight.

It is clear from the above reports and previous laboratory studies that tap-water enemas can indeed be instruments of harm and even death. As the usual colonic irrigation technique employs tap water, it is desirable to establish criteria for assessing, risk. A review of the mechanisms involved in water intoxication is of interest at this point.
When hypotonic solution such as tap water is placed in the colon, it creates a "water reservoir" which is rapidly absorbed by passive diffusion into the osmotically concentrated fluids of the capillary network and interstitial spaces of the colonic tissue. At the same time, there is a net loss of electrolytes into this hypotonic reservoir. As circulating plasma concentrations of electrolytes decrease and plasma water increases, tissue cells are also forced to equilibrate water and electrolytes resulting in tissue edema, including increased intracranial pressure. Thus, the clinical findings in cases of acute water intoxication are those of hyponatremia, hypokalemia, acid-base imbalance and increased intracranial pressure.

Since the mechanism of water intoxication involves osmotic and electrochemical forces acting upon the semi permeable membranes of the gut mucosa, capillaries, and tissue cells of the body, the extent to which it occurs in any case will be determined by:

1. The initial osmolality of fluids on either side of these membranes. Pre-existing depletion may be due to dietary restriction, intravenous fluid administration, hemorrhage, renal disease, and heart failure.

2. The total surface area of membrane in contact with the hypotonic reservoir within the gut lumen, a function of the degree of stretch of colonic mucosa caused by the hydrostatic pressure of the enema fluid. This surface area is larger in patients with atonic colons.

3. The duration of retention of the hypotonic solution, a function of gut motility and enema technique. This factor provides increased risk for patients with local or systemic neurologic deficits such as congenital megacolon or spinal paralysis.

4. The total volume of the hypotonic solution and body fluids within the patient.

5. The ability of the kidney to excrete dilute urine to recover from water overload.

6. Hydrostatic pressure in the colon.

Important differences exist between conventional enemas and colonic irrigation of the type used in the present study. First, enemas are usually a measured volume, typically one-half liter for children and one to three liters for adults. Many colonic irrigation instruments, including the one used in our study, provide no means of volume measurement. However, most of the reported cases of water intoxication following enema, such as Hiatt's series of five cases, occurred with enemas amounting to about two times the volume of conventional enemas. Colon therapists using visible water tanks generally think that several gallons of water are used in the typical 45 minute treatment. In our study, most patients underwent 18 to 20 intake-output cycles per treatment, and many remarked that they felt the volume of water used was very large compared.

Secondly, enemas are usually expelled in a sitting position after brief retention, while colonic irrigation fluid is expelled in lying position under the therapist's control.
Colonic irrigation probably allows for longer retention of water in the colon than enemas.

The data presented in this study supposes the safety of an hypotonic solution in patients with normal bowel tone who are not at risk of acute water intoxication. Further study is warranted to determine the effect of colonic irrigation on water and electrolyte balance in patients with impaired colonic motility, with attention to volume and duration of water infused.

Table 1. Serum Electrolyte Levels Pre & Post Colon Hydrotherapy Treatment

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<th>Potassium</th>
<th>Calcium</th>
<th>Phosphorus</th>
<th>Chloride</th>
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<td>.30</td>
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<td>Mean</td>
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</table>

Figure 1. Pre/Post Colonic Potassium Levels

[Chart showing serum potassium levels for patients K1, K2, K3 with pre- and post-values indicated]
Figure 4. Pre/Post Colonic Serum Calcium Levels.

- Mean Ca1: 9.51
- Mean Ca2: 9.39
- Mean Ca3: 9.37

Figure 5. Pre/Post Colonic Phosphorus Levels.

- Mean P1: 3.72
- Mean P2: 3.52
- Mean P3: 3.58
ELECTROLYTES AND COLONIC IRRIGATION: REFERENCES


Robinson SB, Demuth PL: Diagnostic studies for the aged.


